

## **REMARKS/ARGUMENTS**

Reconsideration of this Application and entry of this Amendment is respectfully requested. Claims 1-25 are pending in the present application. In the Office Action mailed June 28, 2006, the Examiner rejected pending claims 1-25 on various grounds. Claims 1, 6, and 8 are amended and claims 2 and 7 are cancelled herein.

### **37 CFR 1.98(a)(2) IDS**

The information disclosure statement filed on April 18, 2005, was found to be lacking legible copies of each foreign patent document. Legible copies are enclosed herewith.

### **35 U.S.C. §102 Rejections**

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102(b) rejection, the references cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the cited references fail to do so.

- A. Claims 6-10 and 22 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,096,070 to Ragheb, *et al.* (the *Ragheb* patent).

The Applicant respectfully asserts that the *Ragheb* patent fails to teach or suggest all the claim limitations. The *Ragheb* patent fails to disclose, teach, or suggest:

A coated stent with the first coating section disposed on the first region and comprising a first polymer; and a second coating section, the second coating section disposed on the second region and comprising a second polymer, as recited in independent claim 6; or

A coated stent with a first polymer including a first therapeutic agent, the first polymer disposed on the discrete first region; and a second polymer including a second therapeutic agent, the second polymer disposed on the discrete second region, as recited in independent claim 22.

At most, the *Ragheb* patent discloses coated implantable medical device with two bioactive materials 18 and 18' posited on the same surface of base material 14 of structure 12. A

porous layer 20 may be deposited over the bioactive materials 18 and 18' as well as the bioactive-material-free surface of based material 14. *See* Fig. 6B; column 16, lines 13-18. Nothing in the *Ragheb* patent discloses a first polymer and a second polymer, or the first polymer and second polymers including a therapeutic agent, as claimed.

Claims 8-10 depend directly or indirectly from independent claim 6 and so include all the elements and limitations of their independent claim. The Applicant therefore respectfully submits that the dependent claims are allowable over the *Ragheb* patent for at least the same reasons as set forth above with respect to their independent claim.

Withdrawal of the rejection of claims 6, 8-10 and 22 under 35 U.S.C. §102(b) as being anticipated by the *Ragheb* patent is respectfully requested.

- B.** Claims 11, 13-17, 18, 20, and 21 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 6,616,765 to Castro, *et al.* (the *Castro* patent).

The Applicant respectfully asserts that the *Castro* patent fails to teach or suggest all the claim limitations. The *Castro* patent fails to disclose, teach, or suggest:

A method for producing a coated stent including mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; and mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution, as recited in independent claim 11; or

A system for producing a coated stent including means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution, as recited in independent claim 18.

At most, the *Castro* patent discloses that the solvent can be any single solvent or a combination of solvents capable of dissolving the polymer. The particular solvent or combination of solvents selected is dependent on factors such as the material from which prosthesis 12 is made and the particular polymer selected. *See* column 11, lines 55-59. While the *Castro* patent discloses a second composition 80 can be deposited onto prosthesis 12 concurrent with or subsequent to the application of composition 10 to prosthesis 12, and that the second composition 80 may differ from first composition 10 in the particular polymer(s) or monomer(s) selected, the concentration of polymer(s) or monomer(s), the particular therapeutic

substance(s) selected, the concentration of the therapeutic substance(s), or a combination thereof (See column 17, line 61 through column 18, line 2), the *Castro* patent fails to disclose use of different solvents in the polymer solutions for the different regions, as claimed.

Claims 13-17 and claims 20-21 depend directly or indirectly from independent claims 11 and 18, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore respectfully submits that the dependent claims are allowable over the *Castro* patent for at least the same reasons as set forth above with respect to their respective independent claims.

Withdrawal of the rejection of claims 11, 13-17, 18, 20, and 21 under 35 U.S.C. §102(b) as being anticipated by the *Castro* patent is respectfully requested.

### 35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. See MPEP 2143. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

- C. Claims 1-5 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Ragheb* patent in view of U.S. Patent Publication No. 20030181973 to Sahota (the *Sahota* application).

The Applicant respectfully asserts that the *Ragheb* patent and the *Sahota* application, alone or in combination, fail to fail to teach or suggest all the claim limitations. As discussed in Section A above, the *Ragheb* patent fails to disclose, teach, or suggest a stent with the first coating section disposed on the first region and comprising a first polymer; and a second coating section, the second coating section disposed on the second region and comprising a second polymer, as recited in independent claim 1. The *Sahota* application also fails to disclose, teach, or suggest these elements.

Claims 3-5 depend directly or indirectly from independent claim 1 and so include all the elements and limitations of their respective independent claim. The Applicant therefore respectfully submits that the dependent claims are allowable over the *Ragheb* patent and the *Sahota* application for at least the same reasons as set forth above with respect to their respective independent claim.

Withdrawal of the rejection of claims 1 and 3-5 under 35 U.S.C. §103(a) as being unpatentable over the *Ragheb* patent in view of the *Sahota* application is respectfully requested.

- D.** Claims 23-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Ragheb* patent in view of U.S. Patent Publication No. 20020010505 to Richter (the *Richter* application).

The Applicant respectfully asserts that the *Ragheb* patent and the *Richter* application, alone or in combination, fail to fail to teach or suggest all the claim limitations. As discussed in Section A above, the *Ragheb* patent fails to disclose, teach, or suggest a coated stent with a first polymer including a first therapeutic agent, the first polymer disposed on the discrete first region; and a second polymer including a second therapeutic agent, the second polymer disposed on the discrete second region, as recited in independent claim 22. The *Richter* application also fails to disclose, teach, or suggest these elements.

Claims 23-25 depend directly or indirectly from independent claim 22 and so include all the elements and limitations of their independent claim. The Applicant therefore respectfully submits that the dependent claims are allowable over the *Ragheb* patent and the *Richter* application for at least the same reasons as set forth above with respect to their independent claim.

Withdrawal of the rejection of claims 23-25 under 35 U.S.C. §103(a) as being unpatentable over the *Ragheb* patent in view of the *Richter* application is respectfully requested.

- E. Claims 12 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Castro* patent in view of the *Richter* application.

The Applicant respectfully asserts that the *Castro* patent and the *Richter* application, alone or in combination, fail to fail to teach or suggest all the claim limitations. As discussed in Section B above, the *Castro* patent fails to disclose, teach, or suggest: a method for producing a coated stent including mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; and mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution, as recited in independent claim 11; or a system for producing a coated stent including means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution, as recited in independent claim 18. The *Richter* application also fails to disclose, teach, or suggest these elements.

Claim 12 and claim 19 depend directly or indirectly from independent claims 11 and 18, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore respectfully submits that the dependent claims are allowable over the *Castro* patent and the *Richter* application for at least the same reasons as set forth above with respect to their respective independent claims.

Withdrawal of the rejection of claims 12 and 19 under 35 U.S.C. §103(a) as being unpatentable over the *Castro* patent in view of the *Richter* application is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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